

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

① BLACK BORDERS

- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:
03.09.1997 Bulletin 1997/36

(51) Int Cl⁶: **A61M 25/01**

(21) Application number: **97300992.1**

(22) Date of filing: **17.02.1997**

(84) Designated Contracting States:
DE ES FR GB IT

(30) Priority **29.02.1996 US 609154**

(71) Applicant: **Becton Dickinson and Company**
Franklin Lakes, New Jersey 07417-1880 (US)

(72) Inventors
• **Crawford, Mark A.**
Sandy, Utah 84092 (US)

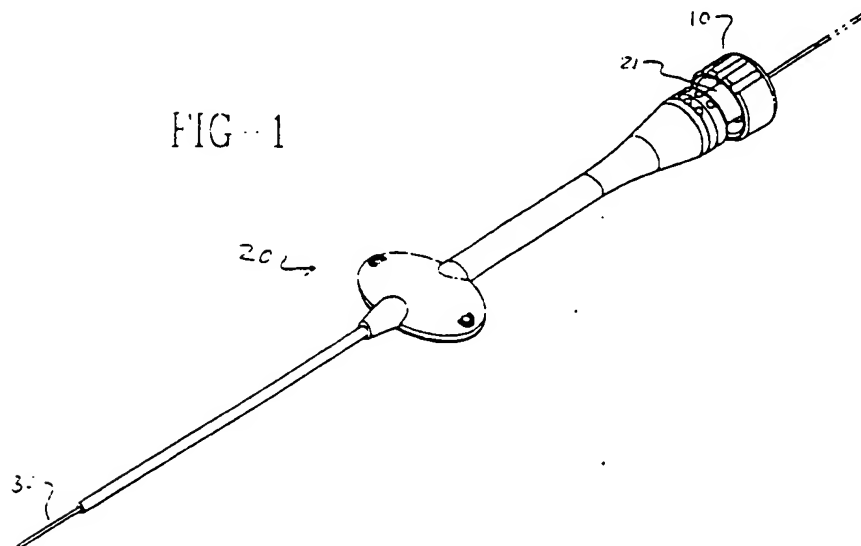
• **Howell, Glade H.**
Sandy, Utah 84094 (US)
• **Musgrave, Kenneth C.**
Sandy, Utah 89092 (US)
• **Erskine, Timothy J.**
Sandy, Utah 84092 (US)

(74) Representative **Ruffles, Graham Keith**
MARKS & CLERK,
57-60 Lincoln's Inn Fields
London WC2A 3LS (GB)

(54) **Guidewire retention device**

(57) A guidewire retention device for use with a catheter or other medical device is disclosed herein. The guidewire retention device can be connected to a standard adapter at the proximal end of the catheter. It has an opening therein which can be placed in communication with the catheter lumen. This opening includes a large diameter portion and a small diameter portion and is preferably keyhole shaped. The large diameter por-

tion allows a guidewire to easily pass therethrough while the small diameter portion does not. Thus, when a guidewire is located in the catheter lumen in the proper position, the guidewire can be fitted into the small diameter portion of the keyhole shaped opening to lock the guidewire with respect to the catheter. A raised icon on the guidewire retention device provides an indication to the clinician of how to use the guidewire retention device.



Description

Background of the Invention

This invention relates to a device that retains a guidewire in position with respect to a catheter. This invention has particular applicability to peripherally inserted central catheters (PICCs) but may also be useful with other catheters where guidewires are used to properly place the catheter in a patient's anatomy.

PICCs are typically used for IV therapy when the medicaments to be provided to the patient must be diluted quickly in the larger central veins of the patient, such as the auxiliary, subclavian or brachiocephalic vein or the superior vena cava, or could otherwise damage the smaller veins in the patient's hand or arm. In the past, central venous access catheters were used. Such catheters are placed directly into these larger veins by a physician. In contrast, PICCs are inserted peripherally into a vein in the patient's arm and maneuvered through the patient's venous system until the distal tip of the catheter is located in the superior vena cava.

In order to properly place a PICC into a patient, a guidewire may be used. These guidewires are generally made from some metal or alloy. Thus, they tend to be stiffer than a standard PICC which is made from a soft flexible polymer such as silicone. When a guidewire is inserted into the catheter, the resulting structure is stiffer and thus more easily maneuvered through the patient's venous system so the distal tip of the catheter can be properly located.

It is important for the distal tip of the catheter and the distal tip of the guidewire to be substantially aligned. This ensures that the distal tip of the catheter remains relatively rigid for maneuverability and that the distal tip of the guidewire does not extend beyond the distal tip of the catheter to cause damage to the blood vessel or to adversely affect maneuverability. Unfortunately, current PICCs and guidewires do not have any simple mechanism to prevent unwanted relative axial movement between the guidewire and the catheter. Instead, the clinician typically bends the guidewire at the point that the guidewire exits the proximal end of the catheter by the luer adapter. This technique is insufficient because it does not positively maintain the relative axial position between the catheter and the guidewire. In addition, this technique damages the guidewire so that if there were any need to advance the guidewire through the catheter, the bend in the guidewire would make this difficult.

Summary of the Invention

It is therefore an object of this invention to provide a mechanism for use with a catheter that maintains the relative axial position of the catheter and a guidewire.

It is another object of this invention to provide a mechanism for use with a catheter that maintains the

relative axial position of the catheter and a guidewire without damaging the guidewire.

The guidewire retention device of this invention comprises a standard male luer adapter defining a lumen therein and having a proximal face with an opening comprising a large diameter portion and a small diameter portion, i.e. a keyhole shaped opening, therein. This keyhole shaped opening is in communication with the lumen that extends through the male luer adapter. The male luer adapter allows the guidewire retention device to be connected to a standard female luer adapter on the proximal end of the catheter so that the lumen in the male luer adapter is in communication with the catheter lumen. This allows a guidewire to extend through the catheter and the guidewire retention device. The keyhole shaped opening is provided with suitable dimensions such that the large diameter portion of the opening allows a guidewire to easily pass therethrough while the small diameter portion mechanically and frictionally engages the guidewire. Thus, when the guidewire retention device is connected to the female luer adapter on the proximal end of the catheter, a guidewire can extend through the catheter, the lumen of the male luer adapter of the guidewire retention device and the large diameter portion of the keyhole shaped opening. When the clinician aligns the distal ends of the catheter and the guidewire, the clinician can move the proximal portion of the guidewire into the small diameter portion of the keyhole shaped opening so the guidewire is locked in place relative to the catheter.

Brief Description of the Drawings

The above and other objects and advantages of this invention will be apparent from the detailed description and drawings in which like parts are referred to by like numbers throughout and in which:

FIG. 1 is a perspective view of a PICC and the guidewire retention device of this invention and a guidewire extending therethrough.

FIG. 2 is a rear elevation view of the guidewire retention device of this invention attached to the proximal end of the PICC as shown in FIG. 1.

FIG. 3 is a rear perspective view of the guidewire retention device of this invention.

FIG. 4 is a front elevation view of the guidewire retention device of this invention.

FIG. 5 is a front perspective view of the guidewire retention device of this invention, and

FIG. 6 is a cross-sectional view of the guidewire retention device of this invention taken along line 6-6 of FIG. 4.

Detailed Description of the Invention

The guidewire retention device 10 of this invention is shown for use in connection with a PICC 20. However,

it is to be understood that guidewire retention device 10 could be used with other catheters or medical devices where guidewire position relative to the catheter or medical device is important

Guidewire retention device 10 includes a male luer adapter portion 11 and a cap portion 14. Guidewire retention device 10 may have a cross-section of any shape. However, guidewire retention device 10 preferably has an elliptical cross-section. Alternatively, guidewire retention device 10 could have a cross-section in the shape of an opening 17 formed therein. See discussion below concerning the configuration of opening 17. In addition, guidewire retention device 10 is formed from a relatively hard plastic such as polypropylene or polycarbonate.

Male luer adapter portion 11 defines an inner lumen 12 that extends therethrough. The outer surface of male luer portion 11 defines a luer slip configuration so that guidewire retention device 10 can be connected to the female luer adapter 21 of catheter 20. Alternatively, male luer adapter portion 11 could have a cylindrical configuration and the interior of cap portion 14 could be configured to include threads that engage the threads of female luer adapter 21. This alternative configuration would provide a greater mechanical connection between guidewire retention device 10 and catheter 20.

Cap portion 14 defines end face 15 and shroud 16. End face 15 defines opening 17 therein that is in communication with lumen 12. Opening 17 includes a large diameter portion 17a and a small diameter portion 17b. Opening 17 is preferably keyhole shaped. However, it is to be understood that opening 17 could have another configuration that includes a large diameter portion that allows a guidewire 30 to pass through and a small diameter portion that engages guidewire 30. See FIG. 1 to prevent movement therebetween. Preferably opening 17 is axially aligned with lumen 12.

Large diameter portion 17a should have a diameter slightly larger than the diameter of guidewire 30 that is to be used with catheter 20. Small diameter portion 17b should have a diameter less than the diameter of guidewire 30. This diameter should be between about 0.001 inches to about 0.010 inches smaller than the diameter of guidewire 30. Preferably the diameter of small diameter portion 17b is about 0.006 inches less than the diameter of guidewire 30. Preferably the sidewalls of small diameter portion 17b define knife edges. See FIG. 6. These knife edges preferably define an included angle, i.e. an angle between the sidewalls of small diameter portion 17b, of about 13.4 degrees, although an angle of between about 6 degrees and about 20 degrees would work. By forming the sides of small diameter portion 17b into knife edges guidewire 30 can be more effectively locked in small diameter portion 17b.

When guidewire 30 is aligned with large diameter portion 17a, guidewire 30 can freely move therethrough so the clinician can easily move guidewire 30 axially relative to catheter 20. This facilitates alignment of the dis-

tal tip of guidewire 30 with the distal tip of catheter 20 when guidewire 30 extends through lumen 22 of catheter 20. Once guidewire 30 and catheter 20 are properly axially aligned, the clinician can move guidewire 30 into small diameter portion 17b. Because small diameter portion 17b has a smaller diameter than guidewire 30, the edges of small diameter portion 17b mechanically and frictionally engage guidewire 30 effectively to lock guidewire 30 with respect to catheter 20.

Endface 15 may also include a raised icon 18 formed thereon. This provides the clinician with an indication of how guidewire 30 should be moved in opening 17 to "lock" or "unlock" guidewire 30 from guidewire retention device 10. Since opening 17 is quite small, raised icon 18 facilitates easy use of guidewire retention device 10.

Preferably raised icon 18 has a keyhole shape. However, raised icon 18 does not have to be keyhole shaped but could have another shape that indicates the direction that guidewire 30 must be moved in order to lock and unlock guidewire 30 from guidewire retention device 10. In addition, as discussed above, endface 15 could be formed into the shape of opening 17 to provide this indication. In this circumstance there would be no need for raised icon 18.

Shroud 16 should be long enough so that the clinician can easily grasp guidewire retention device 10. A plurality of grooves 19 may be formed in shroud 16 to facilitate grasping guidewire retention device 10 by the clinician.

Thus, it is seen that a guidewire retention device is provided that maintains the relative axial position of a catheter and a guidewire without damaging the guidewire.

Claims

1. A guidewire retention device comprising

A tubular portion having a proximal end and a distal end and a lumen extending therethrough; and

a cap portion affixed to the proximal end of the tubular portion, the cap portion defining an opening therein in communication with the lumen wherein the opening has a large diameter portion and a small diameter portion.

2. The guidewire retention device of claim 1 further comprising a raised icon on the cap portion.

3. The guidewire retention device of claim 2 wherein the opening and the raised icon are keyhole shaped.

4. The guidewire retention device of claim 1 wherein the small diameter portion is defined by sidewalls

having an included angle between the sidewalls of
between about 6 degrees and about 20 degrees.

5

10

15

20

25

30

35

40

45

50

55

4

FIG-1

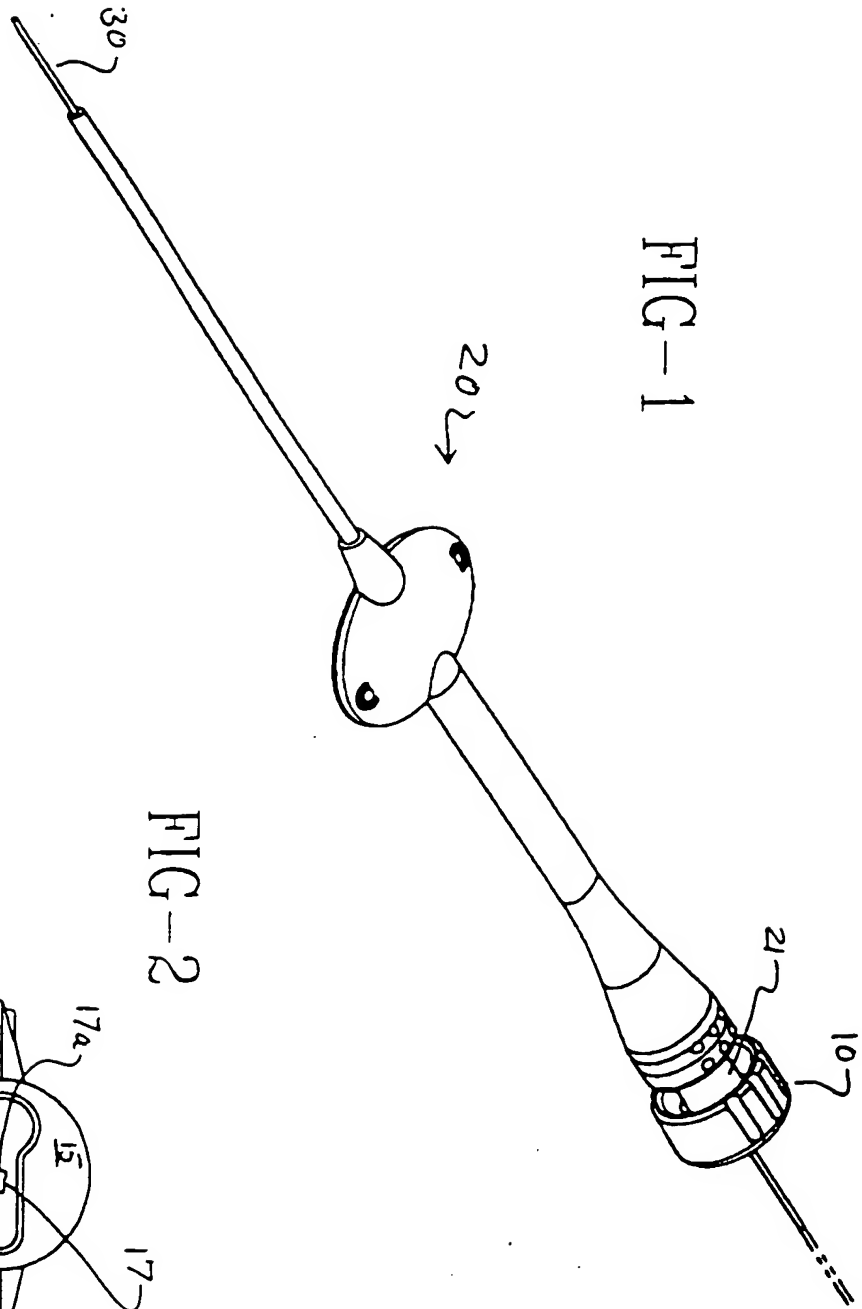


FIG-2

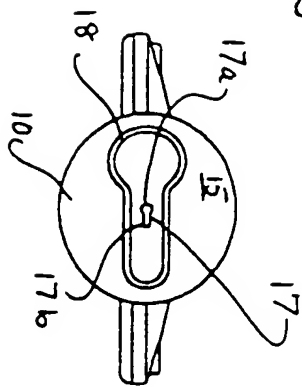


FIG-3

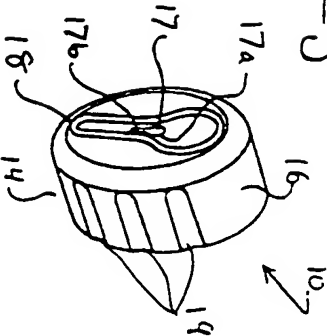


FIG-4

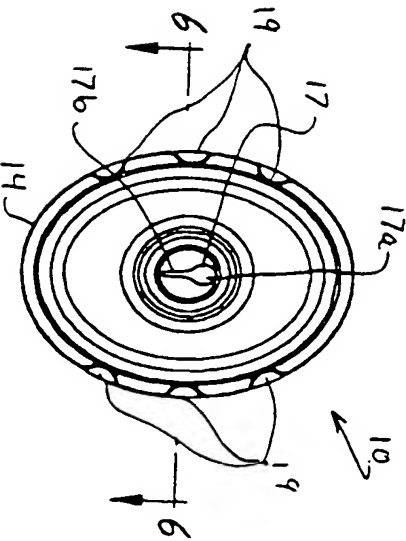


FIG-5

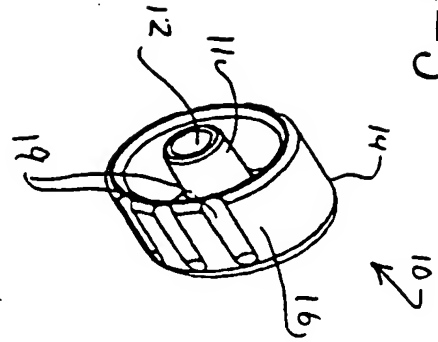
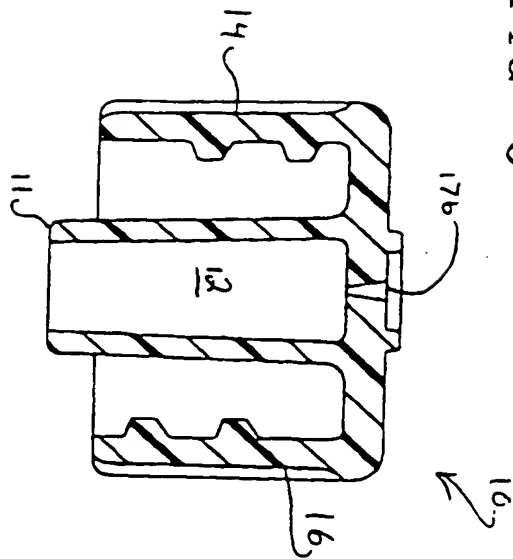


FIG-6



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 30 0992

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication where appropriate of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	FR 2 522 507 A (LABORATOIRE PHARMACEUTIQUE IVERMED) - page 4, line 24 - page 5, line 26 - - figures 1,2 -		A61M25/01
X	US 5 217 435 A (KRING) - column 4, line 1 - line 53 - - figure 2 -	1	
X	WO 94 12094 A (MERIT MEDICAL SYSTEMS, INC.) - page 7, line 18 - page 8, line 22 - - page 11, line 5 - page 12, line 12 - - figures 1-5, 16-23 -	1	
A		12,3	
A	FR 2 620 340 A (AUGER) - page 2, line 5 - line 10 - - figures 1,2 -	3	

TECHNICAL FIELDS
SEARCHED (Int.Cl.6)

A61M

The present search report has been prepared for all claims

THE HAGUE	8 December 1997	Schonleben, J
CATEGORY OF CITED DOCUMENTS 1. DOCUMENTS RELEVANT TO THE INVENTION 2. DOCUMENTS RELEVANT TO THE PRIOR ART 3. DOCUMENTS RELEVANT TO THE STATE OF THE ART 4. DOCUMENTS RELEVANT TO THE STATE OF THE ART 5. DOCUMENTS RELEVANT TO THE STATE OF THE ART 6. DOCUMENTS RELEVANT TO THE STATE OF THE ART 7. DOCUMENTS RELEVANT TO THE STATE OF THE ART 8. DOCUMENTS RELEVANT TO THE STATE OF THE ART 9. DOCUMENTS RELEVANT TO THE STATE OF THE ART 10. DOCUMENTS RELEVANT TO THE STATE OF THE ART 11. DOCUMENTS RELEVANT TO THE STATE OF THE ART 12. DOCUMENTS RELEVANT TO THE STATE OF THE ART 13. DOCUMENTS RELEVANT TO THE STATE OF THE ART 14. DOCUMENTS RELEVANT TO THE STATE OF THE ART 15. DOCUMENTS RELEVANT TO THE STATE OF THE ART 16. DOCUMENTS RELEVANT TO THE STATE OF THE ART 17. DOCUMENTS RELEVANT TO THE STATE OF THE ART 18. DOCUMENTS RELEVANT TO THE STATE OF THE ART 19. DOCUMENTS RELEVANT TO THE STATE OF THE ART 20. DOCUMENTS RELEVANT TO THE STATE OF THE ART 21. DOCUMENTS RELEVANT TO THE STATE OF THE ART 22. DOCUMENTS RELEVANT TO THE STATE OF THE ART 23. DOCUMENTS RELEVANT TO THE STATE OF THE ART 24. DOCUMENTS RELEVANT TO THE STATE OF THE ART 25. DOCUMENTS RELEVANT TO THE STATE OF THE ART 26. DOCUMENTS RELEVANT TO THE STATE OF THE ART 27. DOCUMENTS RELEVANT TO THE STATE OF THE ART 28. DOCUMENTS RELEVANT TO THE STATE OF THE ART 29. DOCUMENTS RELEVANT TO THE STATE OF THE ART 30. DOCUMENTS RELEVANT TO THE STATE OF THE ART 31. DOCUMENTS RELEVANT TO THE STATE OF THE ART 32. DOCUMENTS RELEVANT TO THE STATE OF THE ART 33. DOCUMENTS RELEVANT TO THE STATE OF THE ART 34. DOCUMENTS RELEVANT TO THE STATE OF THE ART 35. DOCUMENTS RELEVANT TO THE STATE OF THE ART 36. DOCUMENTS RELEVANT TO THE STATE OF THE ART 37. DOCUMENTS RELEVANT TO THE STATE OF THE ART 38. DOCUMENTS RELEVANT TO THE STATE OF THE ART 39. DOCUMENTS RELEVANT TO THE STATE OF THE ART 40. DOCUMENTS RELEVANT TO THE STATE OF THE ART 41. DOCUMENTS RELEVANT TO THE STATE OF THE ART 42. DOCUMENTS RELEVANT TO THE STATE OF THE ART 43. DOCUMENTS RELEVANT TO THE STATE OF THE ART 44. DOCUMENTS RELEVANT TO THE STATE OF THE ART 45. DOCUMENTS RELEVANT TO THE STATE OF THE ART 46. DOCUMENTS RELEVANT TO THE STATE OF THE ART 47. DOCUMENTS RELEVANT TO THE STATE OF THE ART 48. DOCUMENTS RELEVANT TO THE STATE OF THE ART 49. DOCUMENTS RELEVANT TO THE STATE OF THE ART 50. DOCUMENTS RELEVANT TO THE STATE OF THE ART 51. DOCUMENTS RELEVANT TO THE STATE OF THE ART 52. DOCUMENTS RELEVANT TO THE STATE OF THE ART 53. DOCUMENTS RELEVANT TO THE STATE OF THE ART 54. DOCUMENTS RELEVANT TO THE STATE OF THE ART 55. DOCUMENTS RELEVANT TO THE STATE OF THE ART 56. DOCUMENTS RELEVANT TO THE STATE OF THE ART 57. DOCUMENTS RELEVANT TO THE STATE OF THE ART 58. DOCUMENTS RELEVANT TO THE STATE OF THE ART 59. DOCUMENTS RELEVANT TO THE STATE OF THE ART 60. DOCUMENTS RELEVANT TO THE STATE OF THE ART 61. DOCUMENTS RELEVANT TO THE STATE OF THE ART 62. DOCUMENTS RELEVANT TO THE STATE OF THE ART 63. DOCUMENTS RELEVANT TO THE STATE OF THE ART 64. DOCUMENTS RELEVANT TO THE STATE OF THE ART 65. DOCUMENTS RELEVANT TO THE STATE OF THE ART 66. DOCUMENTS RELEVANT TO THE STATE OF THE ART 67. DOCUMENTS RELEVANT TO THE STATE OF THE ART 68. DOCUMENTS RELEVANT TO THE STATE OF THE ART 69. DOCUMENTS RELEVANT TO THE STATE OF THE ART 70. DOCUMENTS RELEVANT TO THE STATE OF THE ART 71. DOCUMENTS RELEVANT TO THE STATE OF THE ART 72. DOCUMENTS RELEVANT TO THE STATE OF THE ART 73. DOCUMENTS RELEVANT TO THE STATE OF THE ART 74. DOCUMENTS RELEVANT TO THE STATE OF THE ART 75. DOCUMENTS RELEVANT TO THE STATE OF THE ART 76. DOCUMENTS RELEVANT TO THE STATE OF THE ART 77. DOCUMENTS RELEVANT TO THE STATE OF THE ART 78. DOCUMENTS RELEVANT TO THE STATE OF THE ART 79. DOCUMENTS RELEVANT TO THE STATE OF THE ART 80. DOCUMENTS RELEVANT TO THE STATE OF THE ART 81. DOCUMENTS RELEVANT TO THE STATE OF THE ART 82. DOCUMENTS RELEVANT TO THE STATE OF THE ART 83. DOCUMENTS RELEVANT TO THE STATE OF THE ART 84. DOCUMENTS RELEVANT TO THE STATE OF THE ART 85. DOCUMENTS RELEVANT TO THE STATE OF THE ART 86. DOCUMENTS RELEVANT TO THE STATE OF THE ART 87. DOCUMENTS RELEVANT TO THE STATE OF THE ART 88. DOCUMENTS RELEVANT TO THE STATE OF THE ART 89. DOCUMENTS RELEVANT TO THE STATE OF THE ART 90. DOCUMENTS RELEVANT TO THE STATE OF THE ART 91. DOCUMENTS RELEVANT TO THE STATE OF THE ART 92. DOCUMENTS RELEVANT TO THE STATE OF THE ART 93. DOCUMENTS RELEVANT TO THE STATE OF THE ART 94. DOCUMENTS RELEVANT TO THE STATE OF THE ART 95. DOCUMENTS RELEVANT TO THE STATE OF THE ART 96. DOCUMENTS RELEVANT TO THE STATE OF THE ART 97. DOCUMENTS RELEVANT TO THE STATE OF THE ART 98. DOCUMENTS RELEVANT TO THE STATE OF THE ART 99. DOCUMENTS RELEVANT TO THE STATE OF THE ART 100. DOCUMENTS RELEVANT TO THE STATE OF THE ART		



(11) **EP 0 792 657 A3**

(12) **EUROPEAN PATENT APPLICATION**

(88) Date of publication A3:
 28.01.1998 Bulletin 1998/05

(51) Int Cl. 6: A61M 25/01

(43) Date of publication A2:
 03.09.1997 Bulletin 1997/36

(21) Application number: 97300992.1

(22) Date of filing: 17.02.1997

(84) Designated Contracting States:
 DE ES FR GB IT

(30) Priority 29.02.1996 US 609154

(71) Applicant Becton, Dickinson and Company
 Franklin Lakes, New Jersey 07417-1880 (US)

(72) Inventors
 • Crawford, Mark A.
 Sandy, Utah 84092 (US)

• Howell, Glade H.
 Sandy, Utah 84094 (US)
 • Musgrave, Kenneth C.
 Sandy, Utah 89092 (US)
 • Erskine, Timothy J.
 Sandy, Utah 84092 (US)

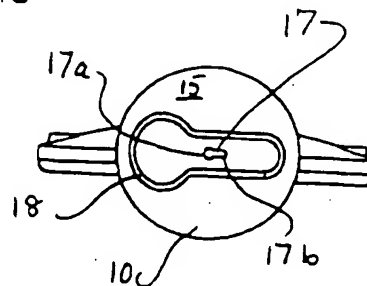
(74) Representative: Ruffles, Graham Keith
 MARKS & CLERK,
 57-60 Lincoln's Inn Fields
 London WC2A 3LS (GB)

(54) **Guidewire retention device**

(57) A guidewire retention device for use with a catheter or other medical device is disclosed herein. The guidewire retention device can be connected to a standard adapter at the proximal end of the catheter. It has an opening therein which can be placed in communication with the catheter lumen. This opening includes a large diameter portion and a small diameter portion and is preferably keyhole shaped. The large diameter por-

tion allows a guidewire to easily pass therethrough while the small diameter portion does not. Thus, when a guidewire is located in the catheter lumen in the proper position, the guidewire can be fitted into the small diameter portion of the keyhole shaped opening to lock the guidewire with respect to the catheter. A raised icon on the guidewire retention device provides an indication to the clinician of how to use the guidewire retention device.

FIG-2



EP 0 792 657 A3